K102922

510(k) Summary

MAY - 4 2011

Device Trade Name HardyCHROM™ MRSA

Intended Use HardyCHROM™ MRSA is a selective and differential chromogenic medium recommended for the qualitative detection of nasal colonization by methicillin-resistant *Staphylococcus aureus* (MRSA) to aid in the prevention and control of MRSA infections in health care settings. The test is performed on anterior nares swabs from patients and healthcare workers to screen for MRSA colonization. HardyCHROM™ MRSA is not intended to diagnose MRSA infection nor to guide or monitor therapy for MRSA infections. Concomitant cultures are necessary to recover organisms for susceptibility testing or epidemiological typing. A negative result does not preclude MRSA nasal colonization.

Device Description HardyCHROM™ MRSA is translucent and light amber in color and contains chromogens that release chromophores when cleaved by enzymes produced by methicillin resistant *Staphylococcus aureus* (MRSA) strains. Based on colony color, HardyCHROM™ MRSA allows for the reliable detection of most MRSA from clinical specimens in less than 24 hours based on the appearance of a pink/magenta colored colony. Non-MRSA strains are either inhibited by the addition of selective agents or utilize different chromogenic substrates in the media to produce different colored colonies. If none of the substrates are utilized, natural or white colored colonies will be present. If plates are negative for growth after 24 hours, it is recommended to re-incubate for an additional 24 hours.

Summary of Performance Data

Interference Studies

Substances that were expected to be associated with MRSA strains in a healthcare setting were evaluated for potential interference of the chromogenic reaction and growth of MRSA strains on HardyCHROM™ MRSA. To serve as a control for this portion of the study, growth was also evaluated on nonselective Trypticase Soy Agar with 5% Sheep Blood (Blood Agar) plates and a commercial chromogenic MRSA medium. Testing included commonly used nasal sprays, bacterial transport devices, mucin, and human blood. Isolates used in these studies included ATCC® control strains of MRSA (ATCC® 33591, ATCC® 43300) and ten clinical well characterized clinical MRSA isolates. The mucin study also included ten well characterized clinical MSSA isolates. The clinical isolates (challenge strains) were obtained from a private culture collection. All isolates were coagulase positive and were characterized by PBP2' and cefoxitin (30 µg) testing.

Interference Study Results – Nasal Sprays

Commonly used nasal sprays that contain a concentration of 1% Phenylephrine Hydrochloride did show an minimal inhibitory affect for microbial growth on the nonselective Blood Agar plates, the HardyCHROM™ MRSA plates, and the commercial chromogenic MRSA medium. Nasal sprays that did not contain this ingredient showed no interference for growth or chromogenic reactions. The sensitivity and specificity criteria of ≥98% were met for the HardyCHROM™ MRSA plates as compared to the commercial chromogenic MRSA medium and Blood Agar plates.

Interference Study Results – Human Blood

Human blood could potentially be associated with MRSA strains in a healthcare setting and therefore was evaluated for potential interference of the chromogenic reaction and growth. Isolates used in this study included ATCC® control strains of MRSA (ATCC® 33591, ATCC® 43300) and ten clinical well characterized clinical MRSA isolates. All strains were evaluated for growth and performance on HardyCHROM™ MRSA, a commercial chromogenic MRSA medium, and Blood Agar plates.

Results demonstrated that none of the MRSA strains were inhibited on the three types of media evaluated, and there was a 100% recovery rate for all strains after exposure to human blood. No discernible difference was observed between the growth and performance testing of HardyCHROM™ MRSA in comparison with nonselective blood agar plates and the commercial chromogenic MRSA medium.

Interference Study Results – Mucin

Nasal swabs containing mucous or mucin were evaluated determine if there was an effect on the chromogenic reaction and the growth of MRSA strains. Isolates used in this study included ATCC® control strains of MRSA (ATCC® 33591, ATCC® 43300), ten clinical well characterized clinical MRSA isolates and ten well characterized clinical MSSA isolates.

All of the strains were evaluated for growth and performance on HardyCHROM™ MRSA and Blood Agar plates. No discernible differences were noted in performance testing of the MRSA strains when compared to the growth on the blood agar plates. Colonies of the MRSA strains grown on HardyCHROM MRSA™ were typical for coloration and size. Counts were stable at 18 hours with no additional growth detected at 24 or 48 hours. All MSSA strains that were tested showed growth only on the blood agar plate and were completely inhibited at 24 and 48 hours on HardyCHROM MRSA™. The results of this study indicate that there is no inhibitory effect of mucin on growth and performance of HardyCHROM MRSA™ medium.

Interference Study Results – Transport Media

Various types of transport media expected to be associated with MRSA strains in a healthcare setting were evaluated for potential interference of the chromogenic reaction and growth. . Isolates used in this study included ATCC® control strains of MRSA (ATCC® 33591, ATCC® 43300) and ten clinical well characterized clinical MRSA isolates. All of the strains were evaluated for growth and performance on HardyCHROM™ MRSA, a commercial chromogenic MRSA medium, and Blood Agar plates. Testing included the following commonly used types transport media: Stuart's Gel, Stuart's Liquid, Amies Liquid, Amies Gel, and Amies Charcoal. Each transport device tested contained rayon-tipped, plastic shaft swabs.

Results demonstrated that none of the MRSA strains were inhibited on the three types of media evaluated, and there was a 100% recovery rate for all transport media devices tested. No discernible difference was observed between the growth and performance testing of HardyCHROM™ MRSA in comparison with nonselective blood agar plates and the commercial chromogenic MRSA medium.

Cross-Reactivity Study

Common types of nasal flora were evaluated for growth and performance on nonselective blood agar plates, HardyCHROM™ MRSA, and a commercial chromogenic MRSA medium. Fresh suspensions were prepared in Tryptic Soy Broth at concentrations of approximately 10^5 to10^6 for the MRSA strains and 10^6 to10^7 for non-MRSA strains. 10µl of these suspensions was used to inoculate the media. A total of 121 strains were tested and included the following genera: *Acinetobacter, Burkholderia, Candida, Corynebacterium, Enterococcus, Enterobacter, Escherichia, Haemophilus, Klebsiella, Leuconostoc, Micrococcus, Moraxella, Neisseria, Proteus, Pseudomonas, Streptococcus and Staphylococcus. Staphylococcus* strains included MRSA, MSSA, and 20 different species of coagulase negative staphylococci (including methicillin resistant *Staphylococcus epidermidis*). HardyCHROM™ MRSA and the commercial chromogenic MRSA medium showed no discernible difference for performance and growth.

Acceptance reproducibility rate of >99% for both inter-lot and overall testing intervals was achieved with the HardyCHROM™ MRSA media. On HardyCHROM™ MRSA medium all of the MRSA strains tested were detected with 24 hours following aerobic incubation at 35-37°C due to their unique pink to magenta colony coloration. Non-MRSA strains that were methicillin resistant either did not grow (i.e. methicillin-resistant *Staphylococcus epidermidis*) or produced blue-colored colonies (*S. intermedius*) that were easily discernible from MRSA strains based on colony color.

Corynebacterium jeikeium had breakthrough growth in the first quadrant at 24 hours with development of a dark purple colored film. Upon further incubation, small dark purple colored colonies were seen at 48 hours. Other strains of bacteria and yeast were inhibited by the selective agents included in the media.

Recovery Study (Limit of Detection (LoD))

On HardyCHROM™ MRSA medium, MRSA strains tested were detected beginning at 16 hours with final counts being reported at 24 hours following aerobic incubation at 35°C. Pink to magenta colonies were detected on all dilutions at 16 hours and colony counts were stable from 21 to 24 hours with no increase in the number of colonies counted. All dilutions plated showed typical pink to magenta colony coloration. There was no significant difference in counts noted between the two observers.

Staphylococcus aureus ATCC® 43300 resulted in a 67.6% recovery when present at 10^2 concentration and *Staphylococcus aureus* ATCC® 33591 resulted in a 34.6% recovery at the same dilution. At 10^1, there was 80% recovery and 52.3% recovery respectively. At 10^3 there was no discernible difference in recovery.

Mixed Infection Study

Suspensions of the non-MRSA organisms (*Staphylococcus aureus* MSSA ATCC® 25923 and *E. coli* ATCC® 25922) were prepared at 10^8 and 10^9 and mixed with suspensions of the MRSA strains (*Staphylococcus aureus* MRSA strains (ATCC® 33591 and 43300)) at the detection limit

concentration (10^3 CFU/mL) and plated in duplicate on Blood Agar and on HardyCHROM™ MRSA. On HardyCHROM™ MRSA medium, the MRSA strains tested were detected beginning at 16 hours with final counts being reported at 24 hours following aerobic incubation at 35°C. Pink to magenta colonies were detected on all dilutions at 16 hours and colony counts were stable at 21 to 24 hours with no increase in the number of colony forming units (CFU) counted. All dilutions plated showed typical pink to magenta colony coloration and colony morphology was consistent with the MRSA strains. No breakthrough was noted of any of the non-MRSA strains. Plates were held for 48 hours and there was no change in CFU of MRSA strains nor was there any breakthrough of non-MRSA.

Incubation Study

When compared to traditional culture, 127 of 132 positive MRSA cultures (96.2%) were detected on HardyCHROM™ MRSA at less than or equal to 24 hours. The remaining five MRSA isolates were detected at approximately 48 hours. All testing (clinical and in-house testing) was incubated aerobically (non-CO_2) at 35 to 37 degrees C.

Reproducibility Study with Characterized MRSA & MSSA strains

Reproducibility testing of HardyCHROM™ MRSA was conducted with twenty well-characterized test strains (fifteen MRSA strains that included Pulse-Field Gel Electrophoresis (PFGE) types USA100, USA200, USA300-0114, USA400, USA500, USA600, USA700, USA800, USA1000, USA1100, five a dditional MRSA strains that are representative of prevalent HA-MRSA and CA-MRSA, and five MSSA (including including Hypervirulent MSSA (NRS72) were selected from the most medically important *S. aureus* lineages[1-5]). SF8300 is a wound isolate of pulse-field type USA300-0114, a subtype implicated in severe disease and in numerous outbreaks [1]. All of the characterized test strains were obtained from the University of San Francisco and DNA restriction patterns were determined by pulsed-field gel electrophoresis. [6]

The fifteen strains of MRSA were tested using a suspension containing approximately 10^5 to 10^6 CFU/ml and the five strains of MSSA were tested at a concentration of approximately 10^6 to 10^7. Ten µl of these suspensions were inoculated onto HardyCHROM™ MRSA. The performance of the HardyCHROM™ MRSA at recovery rate (LoD) was not been evaluated.

Three different lots of HardyCHROM™ MRSA plates were tested to determine that the HardyCHROM™ MRSA plates reliably detected MRSA strains across different lots at different time intervals. A commercial chromogenic MRSA medium was also evaluated with the same strains and served as a performance standard.

Acceptance reproducibility rate of 100% for both inter-lot and overall testing intervals was achieved with the HardyCHROM™ MRSA plates media. All of the characterized MRSA strains showed growth and pink to magenta colony coloration within 24 hours following aerobic (non-CO_2) incubation at 35°-37°C. All of the MSSA strains were inhibited with no growth evident after 24 and 48 hours of aerobic incubation at 35°C. No discernible difference was observed between the performance testing of HardyCHROM™ MRSA in comparison with the commercial chromogenic MRSA medium.

CLINICAL STUDIES

Performance Data

HardyCHROM™ MRSA plates were evaluated at three geographically diverse hospitals and clinics using surveillance specimens of anterior nasal swab samples. A total of four hundred forty-three (443) samples were evaluated overall for this study. Positive and negative controls were tested each day of use. Clinical study sites reported the use of rayon tipped plastic shaft Stuart's gel without charcoal, Liquid Stuarts, Amies Charcoal. One test site reported the use of nylon flocked Amies Eswabs.

For the purpose of this study one nasal specimen swab was used to inoculate a Blood Agar plate first followed by a HardyCHROM™ MRSA plate. A second swab from the same patient was used to inoculate a plate of commercial chromogenic MRSA medium. All of the plates were incubated following standard lab procedures for the Blood Agar and the manufacturer's instructions for the commercial chromogenic MRSA medium and for HardyCHROM™ MRSA plates. Both types of chromogenic plates were incubated aerobically at 35°-37°C (non-CO_2) and were read at both 24 and 48 hours of incubation.

Results from HardyCHROM™ MRSA plates after 24 hours of incubation were compared to the traditional culture method of Trypticase Soy Agar with 5% Sheep Blood (Blood Agar). With the Blood Agar plates, colonies suspected to be *S. aureus* were confirmed with a StaphTEX latex agglutination test. Further testing to characterize colonies of MRSA was performed using a PBP2′ test for the detection of penicillin-binding protein 2a and antibiotic disk diffusion methods using an oxacillin disk (1µg) and also a cefoxitin disk (30µg). Disk susceptibility testing was performed and interpreted according to CLSI guidelines contained in M100-S20. HardyCHROM™ MRSA plates were also compared with a commercial chromogenic MRSA medium for overall evaluation of growth and chromogenic performance.

Quality Control

Quality control was performed by each of the three testing sites on receipt of each shipment of the medium and on each day of use. Fresh suspensions of *Staphylococcus aureus* (MRSA) ATCC® 43300 and *Staphylococcus aureus* (MSSA) ATCC® 25923 were prepared in Tryptic Soy Broth at concentrations of approximately 10^5 to10^6 for the MRSA strain and 10^6 to10^7 for MSSA. 10µl of these suspensions were used to inoculate HardyCHROM™ plates. Plates were incubated and examined for 24 and 48 hours for growth of the MRSA strain and inhibition of the MSSA strain. All QC results testing results provided expected reactions at each of the three testing sites on each day tested.

Product performance is summarized below.

Table 1: HardyCHROM™ MRSA vs. Traditional Culture 24 hours

HardyCHROM™ MRSA 24 hours	Traditional Culture 24 hours			Percent Agreement
	MRSA	Non-MRSA*	Total	
MRSA	126	1**	127	Positive Percent Agreement – 93.3% (95% CI 89.6 – 98.4%)
Non-MRSA*	9	307	316	Negative Percent Agreement – 99.7% (95% CI 98.9 – 100%)
Total	135	308	443	

*Organisms producing other types of non-*mec*A resistance were not evaluated on this medium (e.g. MOD-SA and BORSA).

**One MRSA isolate was detected on HardyCHROM™ MRSA that was not detected by traditional culture. Nine MRSA isolates were detected by traditional culture methods, but did not grow on HardyCHROM™ MRSA. Discrepant results were confirmed as MRSA positive by cefoxitin disk diffusion.

Table 2: HardyCHROM™ MRSA vs. Traditional Culture 48 hours

HardyCHROM™ MRSA 48 hours	Traditional Culture 48 hours			Percent Agreement
	MRSA	Non-MRSA*	Total	
MRSA	131	1**	132	Positive Percent Agreement – 97.0% (95% CI 89.6 – 98.5%)
Non-MRSA*	4	307	311	Negative Percent Agreement – 99.7% (95% CI 98.9 – 100%)
Total	135	308	443	

*Organisms producing other types of non-*mec*A resistance were not evaluated on this medium (e.g. MOD-SA and BORSA).

**One MRSA isolate was detected on HardyCHROM™ MRSA that was not detected by traditional culture. Four MRSA isolates were detected by traditional culture methods, but did not grow on HardyCHROM™ MRSA. Discrepant results were confirmed as MRSA positive by cefoxitin disk diffusion.

Table 3: HardyCHROM™ MRSA vs. Commercial Chromogenic MRSA Medium 24 hours

HardyCHROM™ MRSA 24 hours	Commercial Chromogenic Medium 24 hours			Percent Agreement
	MRSA	Non-MRSA*	Total	
MRSA	118	8**	126	Positive Percent Agreement – 98.3% (95% CI 97.5 – 99.3%)
Non-MRSA*	2*	315	317	Negative Percent Agreement – 97.5% (95% CI 98.9 – 100%)
Total	120	323	443	

*Organisms producing other types of non-*mec*A resistance were not evaluated on this medium (e.g. MOD-SA and BORSA).

**Eight MRSA isolates were detected on HardyCHROM™ MRSA that were not detected on the commercial chromogenic MRSA medium. Two MRSA isolates were detected on the commercial chromogenic MRSA medium, but did not grow on HardyCHROM™ MRSA. Discrepant results were confirmed as MRSA positive by cefoxitin disk diffusion.

Table 4: HardyCHROM™ MRSA vs. Commercial Chromogenic MRSA Medium 48 hours

HardyCHROM™ MRSA 48 hours	Commercial Chromogenic MRSA Medium 48 hours		
	MRSA	Non-MRSA*	Total
MRSA	122	10**	132
Non-MRSA*	2	309	311
Total	124	319	443

Percent Agreement

Positive Percent Agreement – 98.4%
(95% CI 97.5 – 99.3%)

Negative Percent Agreement – 96.9%
(95% CI 89.6 – 98.4%)

*Organisms producing other types of non-*mec*A resistance were not evaluated on this medium (e.g. MOD-SA and BORSA).

**Ten MRSA isolates were detected on HardyCHROM™ MRSA that did not grow on the commercial chromogenic MRSA medium. Two MRSA isolates were detected on the commercial chromogenic MRSA medium, but did not grow on HardyCHROM™ MRSA. Discrepant results were confirmed as MRSA positive by cefoxitin disk diffusion.

Table 5: Summary of Agreement

	MRSA	Non-MRSA*
HardyCHROM™ MRSA vs. Traditional Culture 24 hours	93.3% (126/135) (95% CI 89.6 – 98.4%)	99.7% (307/308) (95% CI 98.9 – 100%)
HardyCHROM™ MRSA vs. Traditional Culture 48 hours	97.0% (131/135) 95% CI 89.6 – 98.5%	99.7% (307/308) 95% CI 98.9 – 100%
HardyCHROM™ MRSA vs. Commercial Chromogenic MRSA Medium 24 hours	98.3% (118/120) 95% CI 97.5 – 99.3%	97.5% (315/323) 95% CI 89.6 – 98.4%
HardyCHROM™ MRSA vs. Commercial Chromogenic MRSA Medium 48 hours	98.4% (122/124) 95% CI 97.5 – 99.3%	96.9% (309/319) 95% CI 89.6 – 98.4%

*Organisms producing other types of non-*mec*A resistance were not evaluated on this medium (e.g. MOD-SA and BORSA).

Performance Compared to PBP2', Oxacillin, and Cefoxitin Disk Diffusion

HardyCHROM™ MRSA was also compared to other laboratory test methods commonly used to identify MRSA strains. In this study each clinical testing site evaluated pink/magenta colored colonies growing on the HardyCHROM™ MRSA plates with PBP2' Latex agglutination. Cefoxitin disk (30µg) and oxacillin disk (1µg) diffusion testing was performed to confirm results. Cefoxitin and oxacillin disk susceptibility was performed and interpreted according to CLSI M100-20. Interpretive zone sizes for oxacillin are ≥13 (Susceptible), 11-12 (Indeterminate), and ≤10 (Resistant). Zone sizes for cefoxitin are ≥22 (Susceptible) and ≤21 (Resistant). No differences in the interpretation of susceptibility/resistance were noted between the two disk types.

Sensitivity and specificity compared to these additional methods are shown in Table 6 – 11.

Summary of HardyCHROM™ MRSA with Other Detection Methods

Table 6: HardyCHROM™ MRSA vs. PBP2' 24 hours

HardyCHROM™ MRSA 24 hours	PBP2' Latex Agglutination 24 hours		
	MRSA	Non-MRSA*	Total
MRSA	126	1**	127
Non-MRSA*	9	307	316
Total	135	308	443

Percent Agreement

Positive Percent Agreement – 93.3%
(95% CI 89.6 – 98.4%)

Negative Percent Agreement – 99.7%
(95% CI 98.9 – 100%)

*Organisms producing other types of non-*mec*A resistance were not evaluated on this medium (e.g. MOD-SA and BORSA).
** 1/1 Blood Agar Plate negative specimen was confirmed as MRSA positive by cefoxitin disk diffusion.

Table 7: HardyCHROM™ MRSA vs. PBP2' 48 hours

HardyCHROM™ MRSA 48 hours	PBP2' Latex Agglutination 48 hours		
	MRSA	Non-MRSA*	Total
MRSA	131	1**	132
Non-MRSA*	4	307	311
Total	135	308	443

Percent Agreement

Positive Percent Agreement – 97.0%
(95% CI 89.6 – 98.5%)

Negative Percent Agreement – 99.7%
(95% CI 98.9 – 100%)

*Organisms producing other types of non-*mec*A resistance were not evaluated on this medium (e.g. MOD-SA and BORSA).
** 1/1 Blood Agar Plate negative specimen was confirmed as MRSA positive by cefoxitin disk diffusion.

Table 8: HardyCHROM™ MRSA vs. Cefoxitin Disk 30µg 24 hours

HardyCHROM™ MRSA 24 hours	Cefoxitin 30µg 24 hours		
	MRSA	Non-MRSA*	Total
MRSA	126	1**	127
Non-MRSA*	9	307	316
Total	135	308	443

Percent Agreement

Positive Percent Agreement – 93.3%
(95% CI 89.6 – 98.4%)

Negative Percent Agreement – 99.7%
(95% CI 98.9 – 100%)

*Organisms producing other types of non-*mec*A resistance were not evaluated on this medium (e.g. MOD-SA and BORSA).
** 1/1 Blood Agar Plate negative specimen was confirmed as MRSA positive by cefoxitin disk diffusion.

Table 9: HardyCHROM™ MRSA vs. Cefoxitin 30µg Disk 48 hours

HardyCHROM™ MRSA 48 hours	Cefoxitin 30µg 48 hours			Percent Agreement
	MRSA	Non-MRSA*	Total	
MRSA	131	1**	132	Positive Percent Agreement – 97.0% (95% CI 89.6 – 98.5%)
Non-MRSA*	4	307	311	Negative Percent Agreement – 99.7% (95% CI 98.9 – 100%)
Total	135	308	443	

*Organisms producing other types of non-*mec*A resistance were not evaluated on this medium (e.g. MOD-SA and BORSA).
** 1/1 Blood Agar Plate negative specimen was confirmed as MRSA positive by cefoxitin disk diffusion.

Table 10: HardyCHROM™ MRSA vs. Oxacillin Disk 1µg 24 hours

HardyCHROM™ MRSA 24 hours	Oxacillin 1µg 24 hours			Percent Agreement
	MRSA	Non-MRSA*	Total	
MRSA	126	1**	127	Positive Percent Agreement – 93.3% (95% CI 89.6 – 98.4%)
Non-MRSA*	9	307	316	Negative Percent Agreement – 99.7% (95% CI 98.9 – 100%)
Total	135	308	443	

*Organisms producing other types of non-*mec*A resistance were not evaluated on this medium (e.g. MOD-SA and BORSA).
** 1/1 Blood Agar Plate negative specimen was confirmed as MRSA positive by cefoxitin disk diffusion.

Table 11: HardyCHROM™ MRSA vs. Oxacillin Disk 1µg 48 hours

HardyCHROM™ MRSA 48 hours	Oxacillin Disk 1ug 48 hours			Percent Agreement
	MRSA	Non-MRSA*	Total	
MRSA	131	1**	132	Positive Percent Agreement – 97.0% (95% CI 89.6 – 98.5%)
Non-MRSA*	4	307	311	Negative Percent Agreement – 99.7% (95% CI 98.9 – 100%)
Total	135	308	443	

*Organisms producing other types of non-*mec*A resistance were not evaluated on this medium (e.g. MOD-SA and BORSA).
** 1/1 Blood Agar Plate negative specimen was confirmed as MRSA positive by cefoxitin disk diffusion.

Reproducibility Testing in Clinical Laboratory Setting

Testing of HardyCHROM™ MRSA was evaluated at all three testing sites for three days in triplicate by three different operators using three different lots of media. The challenge strains were clinical isolates obtained from a private culture collection and included ten well characterized MRSA strains and ten well characterized MSSA strains. All isolates were coagulase positive and were characterized by PBP2' and cefoxitin testing. All of the isolates showed expected results.

Fresh suspensions of the well-characterized clinical strains were prepared in Tryptic Soy Broth at concentrations of approximately 10^5 to10^6 for the MRSA strains and 10^6 to10^7 for

MSSA strains. 10µl of these suspensions were used to inoculate HardyCHROM™ plates. The performance of the HardyCHROM™ MRSA at recovery rate (LoD) was not been evaluated.

A reproducibility rate of 100% for both inter-lot and overall testing intervals was achieved with the HardyCHROM™ MRSA media. At each clinical trial site, sensitivity was 100% for the MRSA strains tested with growth and formation of magenta colored colonies within 24 hours on HardyCHROM™ MRSA following aerobic (non-CO_2) incubation at 35°-37°C. The specificity was 100% for MSSA strains which showed no growth after 48 hours of aerobic (non-CO_2) incubation at 35°-37° C.

No discernible differences were observed between performance testing of HardyCHROM™ MRSA in comparison with the commercial chromogenic MRSA medium.

Quality Control Results

Quality control results for both inter-lot and daily testing achieved a 100% acceptance rate with the HardyCHROM™ MRSA medium at each individual site and across all three clinical test sites. Quality control testing was performed upon receipt of the medium and on each day of testing. Fresh suspensions of *Staphylococcus aureus* (MRSA) ATCC® 43300 and *Staphylococcus aureus* (MSSA) ATCC® 25923 were prepared in Tryptic Soy Broth at concentrations of approximately 10^5 to10^6 for the MRSA strain and 10^6 to10^7 for MSSA. 10µl of these suspensions were used to inoculate HardyCHROM™ plates. The control strain, *Staphylococcus aureus* (MRSA) ATCC® 43300 produced growth with typical magenta colony coloration within 24 hours on HardyCHROM™ MRSA following aerobic (non-CO_2) incubation at 35°-37° C. The control strain *Staphylococcus aureus* (MSSA) ATCC® 25923 was inhibited and showed no growth after 48 hours aerobic (non-CO_2) incubation at 35°-37° C.

Statement of Efficacy and Safety

HardyCHROM™ MRSA was tested and compared to traditional culture identification and susceptibility methods as well as a commercial chromogenic MRSA medium. HardyCHROM™ MRSA demonstrated 93.3% agreement to traditional culture at 24 hours and 97.0% agreement at 48 hours for *mecA* mediated MRSA. Agreement was 99.7% for non-MRSA at both 24 and 48 hours. When compared to the commercial chromogenic MRSA medium, HardyCHROM™ MRSA demonstrated 98.3% agreement at 24 hours and 98.4% at 48 hours for mecA mediated MRSA and 97.5% agreement at 24 hours and 96.9% agreement for non-MRSA at 48 hours.

Agreement with PBP2', cefoxitin (30µg) and oxacillin (1µg) disk testing was 93.3% at 24 hours and 97.0% at 48 hours for *mecA* mediated MRSA. Percent agreement was 99.7% for non-MRSA at both 24 and 48 hours.

Hardy Diagnostics confirms that any and all non-confidential data provided in this submission may be released upon request.

Any information available on the safety of this device will be made available to interested persons upon request.

References:

1. **Diep B.A., Stone, GG, Basuino, L, et al.** 2008. The arginine catabolic mobile element and staphylococcal chromosomal cassette *mec* linkage: convergence of virulence and resistance in the USA300 clone of methicillin-resistant *Staphylococcus aureus*. JID **197**:1523-1530.

2. **Wang R, Braughton KR, Kretschemer D, et al.** 2007. Identification of novel cytolytic peptides as key virulence determinants for community-associated MRSA. Nat. Med **13**:1510-1514

3. **Aguiar-Alves F, Medeiros F, Fernandes O, et al.** 2006. New Staphylococcus aureus Genotyping Method Based on Exotoxin (set) Genes. J Clin Micro. **44**:2728-2732.

4. **Li M, Diep BA, Villaruz AE, et al.** 2009. Evolution of virulence in epidemic community- associated methicillin-resistant Staphylococcus aureus. PNAS **106**:5883-5888

5. **Li M, Cheung YC, Hu J, et al.** 2010. Comparative analysis of virulence and toxin expression of global community-associated methicillin-resistant Staphylococcus aureus strains. JID **202(12)**:1866-1876.

6. **Tenover FC, Arbeit RD, Goering RV et al.** 1995. Interpreting chromosomal DNA restriction patterns produced by pulsed-field gel electrophoresis: criteria for bacterial strain typing. J Clin Microbiol **33**:2233-9

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Hardy Diagnostics
c/o Ms. Rene Clasen
Director of Technical Services/R&D
1430 West McCoy Lane
Santa Maria, CA 93455

MAY - 4 2011

Re: K102922
Trade/Device Name: HardyCHROM™ MRSA
Regulation Number: 21 CFR 866.1700
Regulation Name: Culture medium for antimicrobial susceptibility tests.
Regulatory Class: Class II
Product Code: JSO
Dated: April 26, 2011
Received: April 27, 2011

Dear Ms. Clasen

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter

will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use Statement

510(k) Number (if known): K102922

Device Name: HardyCHROM™ MRSA

Indication for Use:

HardyCHROM™ MRSA is a selective and differential chromogenic medium recommended for the qualitative detection of nasal colonization by methicillin-resistant *Staphylococcus aureus* (MRSA) to aid in the prevention and control of MRSA infections in health care settings. The test is performed on anterior nares swabs from patients and healthcare workers to screen for MRSA colonization. HardyCHROM™ MRSA is not intended to diagnose MRSA infection nor to guide or monitor therapy for MRSA infections. Concomitant cultures are necessary for susceptibility testing or epidemiological typing. A negative result does not preclude MRSA nasal colonization.

Prescription Use √ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Freddie L. Poole

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K102922